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## REMARKS

### Introductory Comments

Reconsideration of the above-identified application in view of the above amendments and foregoing arguments is respectfully requested.

Claims 1-4 are pending and are under consideration. The specification and claims 1 and 4 have been amended as explained below. No new matter has been added as a result of these amendments.

### Objection to the Specification

The disclosure was objected to because of several informalities.

Specifically, the Examiner states that on page 50, lines 3 and 9, that text is missing regarding the A.T.C.C. deposit number and date. Applicants have amended the specification to include this required information.

The Examiner states that the address of the A.T.C.C. should be updated. Applicants have amended the specification to update the address of the A.T.C.C.

The Examiner states that the specification references figures, but there are no figures in the specification as noted in the Preliminary Amendment received April 12, 2002. It appears that the Examiner is referring to a Preliminary Amendment submitted by Applicants on February 25, 2002. In this Preliminary Amendment, lines 30-36 of page 8, which refer to the figures, were deleted.

Additionally, Applicants have amended the specification at pages 1 and 62, to update the status of cited patent applications, which are now U.S. patents.

Applicants submit that all of the informalities noted by the Examiner have been addressed and respectfully request withdrawal of the objection to the disclosure.

### Claim Objection

Claim 1 is objected to because the claim references non-elected subject matter, SEQ ID NOS: 1-3. Applicants have amended claim 1 to delete the reference to SEQ ID NOS: 1-3. Applicants reserve the right to pursue SEQ ID NOS: 1-3 in one or more divisional applications. Withdrawal of the objection to claim 1 for this informality is respectfully requested.

### Rejection of Claims 1-4 Under 35 U.S.C. § 112, First Paragraph

Claims 1-4 are rejected under 35 U.S.C. § 112, First Paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, the Examiner states that the "generic claim language of claim 1 does not adequately define: (a) species of fragments or complements of SEQ ID NO: 4, (b) nucleic acids that selectively hybridize to a PS190 defined as SEQ ID NO: 4, and (c) nucleic acids that have at least 50% identity to a sequence from SEQ ID NO: 4 that fall within the realm of the claim." The Examiner also states that one of ordinary skill in the art cannot readily envisage the identity of the members of the genera. Applicants respectfully traverse the rejection.

With respect to the Examiner's statement as to (a) species of fragments or complements of SEQ ID NO: 4, Applicants assert that the claims define at least a definitive polynucleotide, more specifically a polynucleotide having sequence consisting of SEQ ID NO: 4 derived from a PS190 gene. All fragments of this polynucleotide will have definitive amount of matching nucleotides which will carry definitive features of SEQ ID NO: 4, such as the amino acids and epitopes formed from polypeptides synthesized by SEQ ID NO: 4. Thus, fragments of the SEQ ID NO: 4 are adequately defined based on the sequence itself. Additionally, since complements of the sequence can only be defined by the sequence's complementary nucleotides, the complement of SEQ ID NO: 4 is similarly adequately defined.

With respect to the Examiner's statement as to (b) nucleic acids that selectively hybridize to a PS190 defined as SEQ ID NO: 4, Applicants submit that this feature is also adequately defined. As indicated in the specification and pointed out by the Examiner in the Office Action, the hybridizing process is known and well-defined in the art. While one may apply a certain amount of due experimentation, only a finite and small number of molecules will have nucleic acids that hybridizes to a PS190 defined as SEQ ID NO: 4. Thus, Applicants assert that nucleic acids that selectively hybridize to a PS190 defined as SEQ ID NO: 4 is adequately defined by the claim simply from the listing of the sequence itself.

With respect to the Examiner's statement as to (c) nucleic acids that have at least 50% identity to a sequence from SEQ ID NO: 4 that fall within the realm of the claim is not adequately defined from the claim language, Applicants respectfully disagree. Since the claim lists at least one definitive sequence, SEQ ID NO: 4 which has a definitive sequence and length of nucleotides, and methods are available in the art for determining the sequence and length of a polynucleotide, the range of identity to sequence from SEQ ID NO: 4 would be considered adequately defined as well.

While Applicants traverse the Examiner's line of reasoning above, Applicants have amended the claims in an effort to expedite prosecution of the instant claims. Specifically, Applicants have remove the language pertaining to fragments, hybridizing and percent identity from the claims. For these reasons, Applicants respectfully request withdrawal of the rejection of claims 1-4 under under 35 U.S.C. § 112, First Paragraph.

Claims 1-4 are also rejected under 35 U.S.C. § 112, First Paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner contends that claims 1-4 are broadly drawn to polynucleotides, fragments and complements of SEQ ID NO: 4 but that the specification does not enable one of

ordinary skill in the art to definitively assess the incidence of any type of cancer, particularly cancer in a test sample. The Examiner points out to specific passages in the specification in connection with the use of SEQ ID NO: 4 which the Examiner infers simply as methods of tissue typing (page 50, lines 31-35). The Examiner finally states that while the evidence presented in the specification does point to the high occurrence of PS190 nucleotides and SEQ ID NO: 4 in prostate tissues, this is not sufficient in implementing said sequence in a molecular based diagnostic method for prostate cancer. Applicants respectfully traverse this rejection for the reasons set forth below.

Polypeptides as claimed and described in the specification are derived from the polynucleotides as claimed and described in the specification, which in turn are derived from the gene designated as PS190, which is known to be connected to diseases involving the prostate. As known in the art, protein complexes in general may be used as markers for diseases. The usefulness of polynucleotides in the diagnosis of diseases is based on this concept. The detection of PS190 antibodies in order to detect the presence of disease is described on pages 45 and 46 of the specification. The significance of epitopes is described in the specification at page 45. Examples 4-6 and 8 in the specification describe how high levels of expression of mRNA corresponding to SEQ ID NO: 4 and fragments or complements thereof indicate the presence of prostate disease. Additionally, in the specification, Example 9 describes how the detection of a complex is used as an indication of the presence of PS190 mRNA which is an indication of prostate tissue disease, Section C of Example 11b describes how PS190 proteins are detected via known epitopes/antibodies, Example 15 describes how antibodies which specifically bind to PS190 peptides are purified, and Section C of Example 19 (page 79) describes how competitive binding assays using PS190 polynucleotides in connection to antibody binding sites are used as an indication of the presence of PS190 antigen which is an indicator of prostate cancer. Therefore, Applicants respectfully request withdrawal of this rejection of claims 1-4 under 35 U.S.C. § 112, First Paragraph.

On page 7 of the Office Action, the Examiner reiterates the points made above in connection to fragments, complements and hybridization with respect to 35 U.S.C. § 112, First Paragraph, as to enablement. Applicants respectfully traverse these lines of reasoning. The issue of fragments, complements and hybridization have been addressed above and incorporated herein. As indicated above, in order to expedite prosecution of the instant claims, Applicants have amended the claims to remove such language. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1-4 under 35 U.S.C. § 112, First Paragraph, with respect to enablement of these features.

#### Rejection of Claims 1-4 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner asserts that the phrases “capable of selectively hybridizing to the nucleic acid” and “polynucleotide or fragment derived from a PS190 gene” are vague and indefinite. Applicants respectfully traverse this rejection. Applicants’ responses above with respect to these phrases are incorporated herein. However, as indicated above, in order to expedite prosecution of the instant claims, the claims have been amended to remove such phrases. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1-4 under 35 U.S.C. § 112, second paragraph.

#### Rejection of Claims 1-4 Under 35 U.S.C. § 101

Claims 1-4 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific, substantial, credible or asserted utility or a well established utility. Specifically, the Examiner reiterates her position regarding the language of hybridizing and percent identity, as well as the issue of enablement for a method of detecting prostate cancer, all of which have been addressed above. Applicants respectfully traverse the rejection. Applicants’ response above with respect to these issues are incorporated herein.

However, as stated above, in order to expedite prosecution of the instant claims, the claims have been amended to remove such phrases. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1-4 under 35 U.S.C. § 101.

Additionally, on page 9 of the Office Action, the Examiner appears to reject claim 4 specifically as to the sequence encoding at least one PS190 epitope under 35 U.S.C. § 101. Applicants have amended the claim to remove the acronym PS190. However, Applicants respectfully traverse any rejection regarding the use of this phrase under 35 U.S.C. § 101.

Epitope is a well-defined term in the art. Molecular Biology (4<sup>th</sup> Ed., Lodish et al., W. H. Freeman and Company, 2000) defines epitope as the part of an antigen molecule that binds to an antibody, also called an antigenic determinant. Immunobiology (5<sup>th</sup> Ed., Janeway et al., Garland Publishing, 2001) defines epitope as a site on an antigen recognized by an antibody or an antigen receptor. At page 15, lines 10-16, the specification explicitly states "As used herein, 'epitope' means an antigenic determinant of a polypeptide or protein. Conceivably, an epitope can comprise three amino acids in a spatial conformation which is unique to the epitope."

Applicants submit that from what is defined in the specification and in the art, the phrase "epitope derived from an amino acid sequence" is definite as it means a site on an amino acid sequence or antigen which is recognized by an antibody or an antigen receptor. There are no issues regarding enablement with respect to the use of this term. Accordingly, Applicants respectfully request withdrawal of the rejection of claim 4 under 35 U.S.C. § 101.

## CONCLUSION

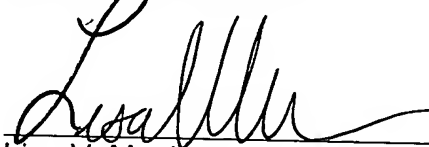
Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Sections 101, 112, 102 and 103. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 23-0785.

Respectfully submitted,

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